

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Offic**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/473, 904 12/28/99 CHEE

M A-67493-2RFT

HM12/0117

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EXAMINER

PRASTHOFER, T

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

01/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/473,904	CHEE ET AL.	
	Examiner Thomas W Prasthofer	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 06 June 2000 and 14 April 2000 and 18 Se.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claims 1-19 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

#### Attachment(s)

15) <input type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	20) <input type="checkbox"/> Other: _____

## ***Detailed Action***

### ***Restriction and Election of Species***

#### ***Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-11, drawn to a composite array, classified in class 536, subclass 25.32.
  - II. Claims 12-17, drawn to a method of decoding an array composition, classified in class 435, subclass 6.
  - III. Claims 18 and 19, drawn to a method of determining the presence of one or more target analytes in one or more samples, classified in class 436, subclass 501.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the composite array of Invention I is used in the process of Invention II which is decoding an array composition. The composite array of Invention I can be

used for other materially different processes than Invention II, including the process of Invention III and other assay-type screening methods.

3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the composite array of Invention I is used in the process of Invention III which is determining the presence of one or more target analytes. The composite array of Invention I can be used for other materially different processes than Invention II, including the process of Invention II and other assay-type screening methods.

4. Inventions II and III are drawn to two different and patentably distinct methods. Invention II is a method of decoding an array composition and Invention III is a method of determining the presence of one or more target analytes. The two Inventions are distinct because they have use different reagents, require different method steps, and result in different outcomes. For example, Invention I includes decoding binding ligands as reagents to identify the location of bioactive agents that are not included in Invention III. Invention II includes the use of first and second substrates and target analytes which are not included in the methods of Invention II. Art anticipating or rendering obvious Invention II would not anticipate or render obvious Invention III. Each invention would support separate patents.

5. Because these inventions are distinct for the reasons given above and
  - a. have acquired a separate status in the art as shown by their different classification ;
  - b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
  - c. have divergent subject matter, restriction for examination purposes as indicated is proper.

*Election of Species*

6. This application contains claims directed to patentably distinct species of the claimed invention. If applicant elects Invention I, applicant is required to elect from the following patentably distinct species.

- A) Species of bioactive agent
- B) Species of identifier binding ligand
- C) Species of optical signature

The species are distinct, each from the other, because they have different chemical, physical, and optical properties, they are used in different processes with arrays of different compositions, and are used to achieve different aims. Therefor, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

7. If applicant elects Invention II, applicant is required to elect from the following patentably distinct species.

- A) Species of bioactive agent
- B) Species of decoding binding ligand
- C) Species of identifier binding ligand

The species are distinct, each from the other, because they have different chemical and physical properties, they are used in different processes with arrays of different compositions, and are used to achieve different aims. Therefor, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

8. If applicant elects Invention III, applicant is required to elect from the following patentably distinct species.

- A) Species of target analyte
- B) Species of bioactive agent

The species are distinct, each from the other, because they have different chemical and physical properties, they are used in different processes with arrays of different compositions, and are used to achieve different aims. Therefor, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

9. Applicant is required under U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally to be allowable.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after election, applicant must indicate which are readable upon the elected species.

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

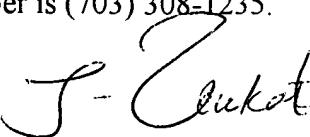
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Thomas W. Prasthofer** whose telephone number is **(703) 308-4548**. The examiner can normally be reached on Monday-Friday, 8:00-4:30.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Thomas Prasthofer, Ph.D.

01/12/01

  
DR. JYOTHSNA VENKAT PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600